

K981254

APR 29 1998

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**ACCUCLOT™ Control II, Cat. No. A5089**

Sigma Diagnostics ACCUCLOT™ Control II is a human plasma control that is suitable for use as a abnormal control with patient citrated plasma in the one-stage prothrombin time (PT), in the activated partial thromboplastin time (APTT), in the chromogenic Antithrombin III (AT-III) assay and in fibrinogen determinations using a clotting method.

The safety and effectiveness of the Sigma Diagnostics ACCUCLOT™ Control II has been demonstrated by its substantial equivalence to the Sigma Diagnostics Coagulation Control, Level II (Cat. No. 8916).

Sigma Diagnostics ACCUCLOT™ Control II is a lyophilized human plasma based product. After reconstitution with water, ACCUCLOT™ Control II is stable for 48 hours when stored at 2-8°C.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

APR 29 1998

William Gilbert, Ph.D.  
Manager, Scientific Affairs  
Sigma Diagnostics Inc.  
545 South Ewing Avenue  
St. Louis, Missouri 63103

Re: K981254  
ACCUCLOT™ Control II  
Regulatory Class: II  
Product Code: GGC, GGN  
Dated: April 2, 1998  
Received: April 6, 1998

Dear Dr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration:

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

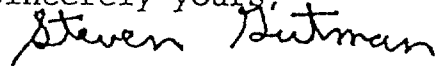
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): 12981254Device Name: Sigma Diagnostics ACCUCLOT™ CONTROL II**Indications For Use:**

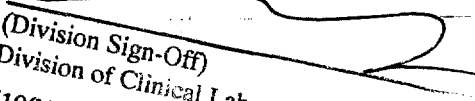
Sigma Diagnostics ACCUCLOT™ CONTROL II is a human plasma control that is suitable for use as an abnormal control with patient citrated plasma in the one-stage prothrombin time (PT), in the activated partial thromboplastin time (APTT), the chromogenic Antithrombin III (AT-III) assay and in fibrinogen determinations using a clotting method. Plasma controls are routinely used in the coagulation laboratory as a means of quality control for coagulation testing.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 12981254

**Prescription Use** \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use** \_\_\_\_\_